

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
v.)	C.A. No. 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC., Defendant.)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
v.)	
NIPPON SHINYAKU CO., LTD. And NS PHARMA, INC., Plaintiff/Counter Defendants.)	

**NS’S RESPONSE TO *DAUBERT* MOTION NO. 3 *TO EXCLUDE*
“STATE OF MIND” OPINIONS OF NS’S EXPERTS**

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Dated: January 12, 2024

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I INTRODUCTION

Defendant-Counterclaim Plaintiffs Sarepta Therapeutics, Inc. and the University of Western Australia’s (together, “Sarepta”) motion seeks to exclude the opinions and testimony of Plaintiff/Counter Defendants Nippon Shinyaku Co. Ltd. and NS Pharma, Inc.’s (together, “NS”) experts Drs. Christine Esau, Michelle Hastings and Matthew Wood wrongly arguing that NS’s experts speculate about Sarepta’s state of mind. For the reasons discussed below, Sarepta’s motion should be denied.

II ARGUMENT

A. Drs. Esau and Hastings Do Not Speculate About Sarepta’s State of Mind in Offering Opinions on Willful Infringement

NS agrees that its experts may not form opinions as to the subjective belief or intent of Sarepta and has no intention of eliciting expert testimony on that issue. NS’s experts can opine, however, on the underlying facts that may show Sarepta’s state of mind. *First Quality Tissue v. Irving Consumer Prods., Ltd.*, No. 19-428, 2022 WL 958089, at *10 (D. Del. Mar. 30, 2022) (differentiating between “expert opinion on intent . . . [versus] Irving’s own ‘stated intent’ from their internal documents”); *Pavo Sols. LLC v. Kingston Tech. Co.*, No. 8:14-cv-1352, 2019 WL 8138163, at *13 (C.D. Cal. Nov. 20, 2019) (“courts have allowed technical experts to testify regarding willful infringement, where their opinions drew, ‘at least in part, on [] technical conclusions.’”), *aff’d*, 35 F.4th 1367 (Fed. Cir. 2022); *Sound View Innovations, LLC v. Hulu, LLC*, No. 17-04146, 2019 WL 4640393, at *6 (C.D. Cal. Aug. 5, 2019) (“[O]pinions are appropriate to the extent that they address the technical information available to Defendant[.]”); *Imperium IP Holdings (Cayman), Ltd. v. Samsung Elecs. Co.*, No. 4:14-cv-371, 2016 WL 3746523, at *2 (E.D. Tex. Jan. 28, 2016) (allowing expert testimony on “technical conclusions” relating to willfulness, “particularly . . . that defendants should have known of the high risk of infringement”).

As Dr. Esau explained in her Reply Report, her willfulness opinions are not based on “speculation” about Sarepta’s state of mind. Rather, she based her opinions on evidence regarding

[REDACTED] D.I. 427 (Ex. 4) Esau Opening *e.g.*, ¶ 209 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As to Dr. Hastings, she explained why, in her opinion, “Sarepta’s alleged invalidity positions and allegations of withholding information from the Patent Office lack merit and are not reasonable.” D.I. 427 (Ex. 7) Hasting Reply ¶ 84 (citing and incorporating her Responsive Report regarding the validity of the NS Patents §§ VIII, IV, X and XI). These technical opinions are relevant to the issue of willfulness and do not improperly speculate about Sarepta’s state of mind.¹

The cases cited by Sarepta are inapposite. For example, in *Zimmer Surgical, Inc. v. Stryker*

¹ [REDACTED]

[REDACTED] As outlined in NS’s Memorandum of Law in Support of its Daubert Motion to Exclude Testimony and Opinions of Steven F. Dowdy, Ph.D, Dr. Dowdy should be precluded from offering any testimony regarding Sarepta’s improperly filed IPRs because any factual findings and legal conclusions from those IPRs have minimal probative value that is substantially outweighed by the potential for prejudice and confusion. D.I. 421 at 9; *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, No. 15-cv-819, 2018 WL 2186677, at *1 (D. Del. May 11, 2018) (Judge Stark) (“Although relevant (for example, to Defendant’s defense to willful infringement), the prejudice and confusion inherent in presenting [evidence regarding PTAB proceedings] to the jury—particularly given the PTAB’s different standards—substantially outweighs its probative value.”).

Corp., the court excluded “expert opinions evaluating [the alleged infringer’s] subjective reliance on the opinions of counsel” from a *patent attorney*, not a technical witness. 365 F. Supp. 3d 466, 497 (D. Del. 2019). *Fuma Int’l, LLC v. R.J. Reynolds Vapor Co.* actually supports the admissibility of Drs. Esau’s and Hastings’s opinions because the Court there determined that an expert’s “technical analysis ... is relevant to the question of willfulness and reliable because it is grounded in [the expert’s] expertise as a mechanical engineer and consumer product designer.” No. 1:19-cv-260, 1:19-cv-660, 2021 WL 4820738, at *2 (M.D.N.C. Oct. 15, 2021). Thus, *Fuma* ultimately held that the expert was “not prohibited from providing opinions about technical aspects of [the defendant’s] alleged infringement that could support a finding of specific intent to infringe.” *Id.* at *3.

Because Drs. Esau’s and Hastings’s willfulness opinions are not based on “speculation” about Sarepta’s state of mind, the Court should deny Sarepta’s motion to preclude their testimony.

B. Dr. Wood Does Not Speculate as to the Named UWA Inventors’ State of Mind in His Evaluation of Conception

Sarepta also moves to exclude Dr. Wood from providing testimony regarding the mental state of the named UWA inventors in providing his opinions on conception. But as Sarepta itself recognized, Dr. Wood’s Reply Report clearly states that he is basing his conception opinions from the perspective of a *POSA* rather than what the named UWA inventors actually believed they had invented. D.I. 395 at 14.² For example, in his Reply Report, Dr. Wood stated: “When I use the term ‘invented’ I am referring to what a POSA would have understood the inventors possessed, recognized, appreciated, conceived, or had a definite and permanent idea of as of the June 28, 2005 filing date of the UWA

² Sarepta complains that “NS appears to be recasting Dr. Wood’s state of mind testimony on conception as an opinion on validity” and argues that [REDACTED]

[REDACTED] *Id.* This issue has been fully briefed (D.I. 385, 387 and 389) and need not be addressed herein.

Patents.” D.I. 425-1 (Ex. 30) at 7 n.3. He further opined, for example, that:

- “a **POSA** would understand the inventors possessed, recognized, or appreciated that there was such ‘hot spot’ or amenable region spanning +23 to +69 downstream of the acceptor site or that 20 to 31 bases or that at least 12 consecutive bases of SEQ ID NO: 195 ...” (*Id. e.g.*, ¶ 13);
- “A **POSA** reviewing the UWA Specification upon its publication as Wilton PCT ’057 would not have understood the inventors to have discovered, possessed, recognized, or appreciated any general properties of exon 53 skipping AONs that alleviated or resolved the unpredictable nature of designing such AONs to induce exon 53 skipping ...”) (*id.* ¶ 14);
- “a **POSA** would not have viewed the UWA Specification as disclosing or identifying a ‘hot spot’ or amenable region for exon 53 skipping.” (*id.* ¶ 17);
- “a **POSA** would not understand the inventors to have had an expectation that AONs of 20 bases would induce exon 53 skipping, or understand that the inventors had invented AONs of less than 25 bases that were capable of inducing exon 53 skipping, regardless of annealing site.” (*id.* ¶ 38);
- “A **POSA** reviewing the UWA Specification in June 2005 would not have understood the inventors to have invented the structural features recited in the claims that were submitted in 2017 ...” (*id.* ¶ 40).

“Conception is complete only when the idea is so clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.” *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994). The inventor must be able to “describe [the] invention with particularity” for a POSA to “understand the invention.” *Id.* at 1228. Because Dr. Wood’s conception opinions are properly based on what a **POSA** would have understood the named inventors to have invented, and not what the named inventors subjectively believed they had invented, the Court should deny Sarepta’s motion to exclude Dr. Wood’s testimony regarding conception.

III CONCLUSION

The Court should deny Sarepta’s motion to preclude the testimony of Drs. Esau, Hastings, and Wood.

Dated: January 12, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

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